DEPARTMENT OF HEALTH AND HUMAN SERVICES

95057d

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

October 22, 2004

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 05-05

Jeffrey M. Golini, President
All American Pharmaceuticals and
Natural Food Corporation
1845 Main Street
Billings, Montana 59105

WARNING LETTER

Dear Mr. Golini:

The Food and Drug Administration (FDA) inspected your firm located at 1831 Main Street, Billings, Montana, on July 8, 2004, and September 8, 9, and 15, 2004. In addition, we have reviewed your website located at the Internet address http://www.allamerican4nutrition.com. Our review of your website and information collected during the inspections, including labels for your products, found numerous violations of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and FDA's regulations through links on FDA's Internet web site at http://www.fda.gov.

Products Containing Androstenedione and/or Other Steroid Prohormones:

The term "dietary supplement" is defined in 21 U.S.C. 321(ff) (section 201(ff) of the Act). Given that you have represented that the androstenedione and other steroid prohormone-containing products you manufacture (AndroBol, DiolBol, AndroMax, and Androstenedione) are dietary supplements, we assume you have a basis to conclude that the steroid prohormone ingredients in these products, i.e., androstenedione, 19-norandrostenedione, and 5-androstene-3b 17b-diol, are "dietary ingredients" under 21 U.S.C. 321(ff)(1). Assuming that androstenedione, 19-norandrostenedione, and 5-androstene-3b 17b-diol are "dietary ingredients," they would also be "new dietary ingredients" for which a notification is required under 21 U.S.C. 350b(a)(2) and 21 CFR 190.6.

Under 21 U.S.C. 350b, a dietary supplement that contains a new dietary ingredient (i.e., a dietary ingredient not marketed in the United States before October 15, 1994) shall be deemed adulterated under 21 U.S.C. 342(f) unless it meets one of two requirements:

1) The dietary supplement contains only dietary ingredients that have been present in the food supply as an article used for food in a form in which the food has not been chemically altered; or
2) There is a history of use or other evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe and, at least 75 days before being introduced or delivered for introduction into interstate commerce, the manufacturer or distributor of the dietary ingredient or dietary supplement provides FDA with information, including any citation to published articles, which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe.

FDA is not aware of any information demonstrating that androstenedione, 19-norandrostenedione, and 5-androstene-3b 17b-diol were lawfully marketed as dietary ingredients in the United States before October 15, 1994. Nor is FDA aware of any information demonstrating that these ingredients have been present in the food supply as articles used for food in a form in which the food has not been chemically altered. In the absence of such information, androstenedione, 19-norandrostenedione, and 5-androstene-3b 17b-diol are subject to the notification requirement for a new dietary ingredient in 21 U.S.C. 350b(a)(2) and 21 CFR 190.6. Because you have not submitted the required notification for these substances, your AndroBol, DiolBol, AndroMax, and Androstenedione products are adulterated under 21 U.S.C. 342(f)(1)(B) and 350b(a).

Even if the required notification had been submitted, based on what we know now, we know of no evidence that would establish that your products are not adulterated. In the absence of history of use or other evidence of safety establishing that androstenedione, 19-norandrostenedione, and 5-androstene-3b 17b-diol, when used under the conditions recommended or suggested in the labeling of your product, will reasonably be expected to be safe, a product containing androstenedione,19-norandrostenedione, or 5-androstene-3b 17b-diol is adulterated under 21 U.S.C. 342(f)(1)(B) and 350b(a) as a dietary supplement that contains a new dietary ingredient for which there is inadequate information to prove reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such a product into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v). FDA is aware of no history of use or other evidence of safety establishing that androstenedione, 19-norandrostenedione, or 5-androstene-3b 17b-diol will reasonably be expected to be safe as a dietary ingredient. In the absence of such history of use or other evidence of safety, your products would be considered adulterated even if you had submitted a notification.

During the inspection of September 8, 9, and 15, 2004, you stated that the lots of AndroBol, DiolBol, AndroMax, and Androstenedione were manufactured for export to London, England. In order to export a dietary supplement that may not be sold in the United States, certain recordkeeping requirements listed in 21 CFR 1.101 must be met to demonstrate compliance with section 801(e)(1) of the Act (21 U.S.C. 381(e)(1)). These records are as follows:

1) Records demonstrating that the product meets the foreign purchaser's specifications;
2) Records demonstrating that the product does not conflict with the laws of the importing country;
3) Records demonstrating that the product is labeled on the outside of the shipping package that it is intended for export; and
4) Records demonstrating that the product is not sold or offered for sale in the United States.

During our inspection, you could provide no documentation to demonstrate your compliance with section 801(e)(1) of the Act. You maintain no documentation to show that the products meet the foreign purchaser's specifications. You could provide no documentation to show that dietary supplements containing androstenedione, 19-norandrostenedione, and 5-androstene-3b 17b-diol are legal in England. You do not label the shipping boxes "for export only" nor could you provide any documentation to show that accompanying paperwork indicates the product is for export only. Finally, you maintain no shipping documents to show the destination of these products, including documents demonstrating that these products are not sold or offered for sale in the United States.

If the requirements of 801(e)(1) are not met, the product cannot legally be exported and is subject to enforcement action under the Act.

We request that you take prompt action to correct these and any other violations associated with AndroBol, DiolBol, AndroMax, and Androstenedione, and any other products manufactured by your firm that contain androstenedione or other steroid prohormones. We also remind you that the new dietary ingredient notification requirement applies to all dietary supplements that contain new dietary ingredients that have not been present in the food supply as articles used for food in a form in which the food has not yet been chemically altered. To date, your firm has not submitted any such notifications.

Dietary Supplements with Disease Claims:

Under section 201(g)(1)(B) of the Act (21 U.S.C. 321(g)(1)(B)), articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease are drugs. Based on claims that appear on your website, we have determined that several of your products are promoted for conditions that cause the products to be drugs under section 201(g)(1)(B). The therapeutic claims on your website establish that the products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease. The marketing of these products with these claims violates the Act and may subject you or the products to regulatory action without further notice.

Examples of some of the claims observed on your website include:

- **Vitamin C Capsules:** "[B]enefits that can be attributed to Vitamin C, including...aiding in the healing of wounds, and increasing the performance of the immune system from the

effects of viral infections such as colds and influenza (which can reduce symptom severity and shorten illness time). Vitamin C...may prevent damage caused to [cells] by cancer, heart disease...and arthritis."

- **B-Complex 100 Capsules:** "[M]ay be useful in treating...depression... ."
- **Vitamin C with Bioflavinoids Capsules:** "[B]enefits that can be attributed to Vitamin C, including...aiding in the healing of wounds, and increasing the performance of the immune system from the effects of viral infections such as colds and influenza (which can reduce symptom severity and shorten illness time). Vitamin C... may prevent damage caused to [cells] by cancer, heart disease...and arthritis."
- **St. John's Wort Capsules:** "[U]sed as a remedy for...depression. It has also been used ...to treat lung diseases and urinary tract infections, and to help heal wounds and cuts."
- **Iron with Vitamin C Capsules:** "[B]enefits that can be attributed to Vitamin C, including...aiding in the healing of wounds, and increasing the performance of the immune system from the effects of viral infections such as colds and influenza (which can reduce symptom severity and shorten illness time). Vitamin C ... may prevent damage caused to [cells] by cancer, heart disease... and arthritis."
- **Wild Yam Capsules:** "[U]sed to help prevent miscarriage... ."
- **Vitamin A Tablets:** "As an antioxidant, it helps protect cells against cancer... ."
- **Anti-Oxidant Capsules:** "[P]rotects cells against cancer... ."
- **Soy Isoflavone Capsules:** "[M]ay play a part in lowering LDL (or "bad" cholesterol) in the blood...and bone loss in menopausal women, and inhibiting the growth of some cancer cells."

Furthermore, because these products are not generally recognized as safe and effective when used as labeled, they are also new drugs as defined in section 201(p) of the Act (21 U.S.C. 321(p)). Under section 505 of the Act (21 U.S.C. 355), a new drug may not be legally marketed in the United States without an approved New Drug Application (NDA).

Dietary Supplement with Unsubstantiated Structure/Function Claim:

Under the Act, dietary supplements may be legally marketed with claims that they affect the structure or function of the body (structure/function claims) if certain requirements are met. Section 403(r)(6)(B) of the Act (21 U.S.C. 343(r)(6)(B)) requires the manufacturer of a dietary supplement containing a "structure/function" claim in the product's labeling to have substantiation that the claim is truthful and not misleading.

Your website contains the following structure/function claim for your Chitosan Capsules product:

- "By taking Chitosan before a meal that contains fat, Chitosan binds to the fats as it passes through the system. Thus, Chitosan *[sic]* been called 'fat blocker.'"

We have reviewed this claim and have concluded that it is not supported by reliable scientific evidence. Because this claim lacks substantiation, it is false or misleading, and causes your product to be misbranded under sections 403(a)(1) and 403(r)(6)(B) of the Act. It is a violation of section 301(a) of the Act (21 U.S.C. 331(a)) to introduce or deliver for introduction into interstate commerce any food, including a dietary supplement, that is misbranded.

Product that Fails to Meet the Definition of "Dietary Supplement":

Your product "MyoPlus Deluxe™ Meal Replacement" is misbranded under section 403(a)(1) of the Act in that the label includes the words "dietary supplement;" however, the product fails to meet the statutory definition for "dietary supplement" under section 201(ff) of the Act. Because this product is represented to be a "meal replacement" on your website and bears a "Nutrition Facts" panel, it is represented for use as a conventional food and a sole item of a meal or the diet (see section 201(ff)(2)(B) of the Act). As a result, this product is a conventional food, not a dietary supplement, and the "dietary supplement" identifier on the product label is false and misleading.

Dietary Supplements with Other Labeling Deviations:

Your products "B-Large™ Low Fat Weight Gainer" and "8th Generation Ionic Whey™ Supreme" are misbranded under section 403(q)(5)(F) of the Act because they are labeled as dietary supplements, but they fail to bear a "Supplement Facts" panel as required under 21 CFR 101.36.

Your products "B-Large™ Low Fat Weight Gainer" and "8th Generation Ionic Whey™ Supreme" are also misbranded under sections 403(i)(1) and 403(s)(2)(B) of the Act because they fail to declare the common or usual name of the food and the labels fail to identify the products by using the term "dietary supplement" (or an appropriate alternative) as specified under 21 CFR 101.3. According to 21 CFR 101.3(g), dietary supplements must be identified by the term "dietary supplement" as part of the statement of identity (or by the appropriate alternative authorized by the regulation). Furthermore, your products "B-Large™ Low Fat Weight Gainer" and "8th Generation Ionic Whey™ Supreme" are misbranded under section 403(f) of the Act because the term "dietary supplement" and statement of identity are not prominently placed on the label in accordance with 21 CFR 101.3(d). According to 21 CFR 101.3(d), the statement of identity must be presented in bold type on the principal display panel and be in a size reasonably related to the most prominent printed matter on such panel. The term "dietary supplement" on these labels does not meet the requirements of sections 403(i)(1), 403(f), and 403(s)(2)(B) because it is not part of the statement of identity and is not reasonably related to the most prominent printed matter on the principal display panel.

Furthermore, in the "All American Quality" section, under the heading "Our In-House Lab," your website states the following: "All inbound raw material will be FDA validated," "All finished products will be FDA validated," and "Your product will meet label claims backed by the only analyzer FDA validated." These statements are false; FDA does not validate or approve your finished products, the raw materials you use, or your laboratory equipment. These false

representations cause the products sold on your website to be misbranded under section 403(a)(1) (for dietary supplements and other foods) or section 502(a)(for drugs) of the Act.

This letter is not intended to be an all inclusive review of your products and labeling. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to immediately cease distribution of your violative products could result in enforcement action by FDA without further notice. The Act provides for the seizure of illegal products, injunctions against the manufacturers and/or distributors of violative products, and criminal sanctions against persons responsible for causing violations of the Act.

Please notify this office in writing within fifteen (15) working days of the receipt of this letter as to the specific steps you have taken to correct these violations, including any steps taken with respect to violative products currently in the marketplace, and an explanation of each step taken to assure that violations do not recur. Your reply should be sent to the Food and Drug Administration, Attention: Lisa Althar, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421.

Sincerely,

Charles M. Breen
District Director

cc: MDHS with disclosure statement

cc: Joseph Rannazzisi, Deputy Director
Office of Diversion Control
Drug Enforcement Administration
Washington, DC 20537